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EXAMINER
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ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,122	BAKER, TONY	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/3/2006 has been entered.

2. Currently, claims 1-51 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections constitute the complete set being presently applied to the instant Application. Any rejection not reiterated is moot in view of the amendments to the claims. Response to Applicant's arguments follow, where applicable.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The rejection made under 35 USC 102(b) as anticipated by Chung is moot in view of the amendments to claims 1, 17, and 37.

Claim Objections

5. Claim 15 is objected to because of the following informalities: The claim contains a typographical error in the duplicate recitation of "selected from the group" in line 2. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. Claims 1-6, 8-13, 15-22, 25-29, 31-41, 43-48, 50 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang (WO 95/35390; 12/28/1995) as evidenced by Harvey I (US Patent 6,168, 922) or Harvey II (US Patent 5,939,259) or Collis (Collis et al; US Patent 5,763,185).

The claims are drawn to a method of suppressing the interference of specific masking agents on a molecular assay of a nucleic acid containing test sample (claims 1 and 17) or a method of improving hybridization of nucleic acids by suppressing specific masking agents (claim 37) comprising contacting the test sample with an amount of a divalent metal chelator and a chelator-enhancing component. With regard to claim 37, the recitation of "test nucleic acid" and "target nucleic acid" are interpreted to be any nucleic acid molecule, respectively.

With regard to claims 1-3, 6, 17-19, 22, and 37-39, Zhang teaches a method comprising adding a lysis buffer containing 2.5-5M guanidine thiocyanate and 100mM EDTA and .5% of a detergent to an equal volume of sample (serum) that contains nucleic acids (test nucleic acids) (it is noted that the final concentration of buffer would be 1.25-2.5 M GnSCN and .05M EDTA) (p. 14, lines 8-30) (claims 4, 5, 8, 9, 20, 21, 24, 25, 40, 41, 43, and 44) and subsequently adding nucleic acid amplification probes (target nucleic acid) and paramagnetic beads to the solution

containing lysis buffer and nucleic acids from the sample. Zhang specifically teaches that hybridization occurs between the nucleic acid from the sample and the probes (p.17, lines 19-20). Zhang specifically teaches that the method can be used for detection of genetic variations in samples from patients with genetic diseases or neoplasia (page 4, lines 13-23, page 5, lines 12-19- eukaryotic DNA).

With regard to claims 31-33, Zhang specifically teaches that samples for the method include whole blood, separated white blood cells, sputum, tissue biopsies, throat swabbings, urine, and serum (see page 13, lines 34-37, page 14, line 11) (claims 31-33).

With regard to the preamble in claims 1, 17, and 37 as well as claims 10-13 and 26-29, although Zhang does not specifically teach inhibition of masking agents set forth in the claim, such is considered a property of the method of Zhang as the addition of the reagents taught by Zhang to the sample taught by Zhang provides for suppression of such masking agents. As evidenced by Harvey ('259), common inhibitors, such as hemoglobin, to nucleic acid amplification can be found in buccal swabs, plasma, serum, sputum, urine and whole blood samples (column 3, lines 55-60). Harvey also teaches that chaotropic salts, such as guanidine thiocyanate (GuSCN) can overcome the problem of hemoglobin inhibition. As evidenced by Collis ('185), nucleic acid hybridization inhibitory substances are derived from heme and hematin which are commonly found in blood samples (col. 1, lines 27-30). Collis teaches that adding chaotropic agents such as guanidine thiocyanate in samples containing inhibitors overcomes this problem (para bridging cols 2-3). With regard to claim 17, which preamble recites "a method of improving the signal response of a molecular assay" and claim 37 which preamble recites "a method of improving hybridization of nucleic acids", such recitations do not

distinguish the instantly claimed methods from those of Zhang because Zhang teaches the positive process steps of the claimed method in the same order, and thus the effects of such necessarily follow. Further, Zhang teaches that wash buffers comprising 1-1.5 M GnSCN and 10 mM EDTA removes unbound proteins that may interfere with subsequent steps (see para bridging pp 17-18).

With regard to claims 36, 48, and 50-51, Zhang teaches molecular assays such as ligation dependent amplification, PCR, and hybridization (abstract, page 33).

Response to Arguments

7. The response traverses the rejection. The response asserts that there is no teaching in Zhang of suppressing interference of a masking agent such as those recited in claim 1. The response asserts that with respect to claims 37-41 and 43-47, there is no teaching of improvement in hybridization attributable to the removal of suppression of the specific masking agents recited in the claims. These arguments have been thoroughly reviewed but were found unpersuasive as such secondary considerations cannot overcome a rejection based on 35 USC 102. Zhang teaches addition of reagents set forth in the claims to samples set forth in the claims. The fact that Zhang did not appreciate such secondary considerations does not overcome the fact that Zhang teaches the same steps as those in the instantly claimed methods. The intended use for the methods does not distinguish the claimed methods over the teaching of Zhang. In the instant case, Zhang teaches the positive process steps of the claimed method in the same order, and the reagents and concentrations used in the method of Zhang are encompassed by instant claims. Therefore, the teachings of Zhang (which include assays which use hybridization and PCR)

would necessarily improve hybridization because the reagents and methods of Zhang are the same as those encompassed by the instantly claimed invention. It is noted that claim 37 simply recites that the amounts of divalent metal chelator and chelator enhancing component are selected such that hybridization is improved. The amounts of Zhang's divalent metal chelator and chelator enhancing component are encompassed by the instant pending claims, and therefore Zhang teaches such amounts. Further, claim 37 recites contacting the test solution with target nucleic acid such that hybridization occurs, which is also taught by Zhang. Therefore, Zhang teaches the positive process steps of the claimed method in the same order, and the preamble of the instantly pending claims does not distinguish the instantly pending claims from the teachings of Zhang. For these reasons and the reasons already made of record, the rejection is maintained.

8. Claims 1-3, 6, 10-13, 15-19, 22, 26-29, 31-32, 34-36, 50 and 51 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Harvey I (Harvey et al; US Patent 6,168, 922; 102(e) date: 4/9/1997) or in the alternative under 35 U.S.C. 102(b) as being anticipated by Harvey II (Harvey et al; US Patent 5,939,259); as defined by Akane et al (Forensic Science, vol. 39, pp 362-372, 1994).

The claims are drawn to a method of suppressing the interference of specific masking agents on a molecular assay of a nucleic acid containing test sample (claims 1 and 17) comprising contacting the test sample with an amount of a divalent metal chelator and a chelator-enhancing component.

With regard to claims 1-3, 6, 15-19, 22, 34-36, 50 and 51, Harvey I and II teach and claim methods and devices for collecting, storing, and purifying nucleic acids such as DNA or

RNA from fluid samples for subsequent genetic characterization by conventional amplification methods (see abstract, claims 1-34 of Harvey I, claims 1-12 of Harvey II) which comprises adding EDTA and guanidine thiocyanate to a test sample containing nucleic acids. With regard to claims 31-33, Harvey I and II specifically teach that the nucleic acids can be either from an untreated blood source such as saliva, serum or urine, or a treated blood source (see abstract, col. 2, lines 54-65) that has naturally occurring nucleic acid amplification inhibitors present, such as hemoglobin (instant claims 1, 17, 10-13, 26-29). Harvey et al teach that the device, 903 paper, should be composed of an absorbent material that does not bind nucleic acids irreversibly, impregnated with a chaotropic salt such as guanidine isothiocyanate or sodium perchlorate. Harvey et al specifically teach a method whereby a square of treated paper (treated with guanidine thiocyanate – see example 1, col. 5) is added to blood which has been collected in a tube containing EDTA (see example 6). Harvey et al teach that DNA was extracted from the paper and subjected to PCR (see figure 7, lanes 9 and 10 which show amplification of product). It is noted that Harvey et al does not teach suppressing the effects of methemoglobin, however such is considered a component of blood samples along with hemoglobin and other oxidation and breakdown products thereof. Hemoglobin was known to inhibit PCR reactions at the time of the invention. Further, such inhibition was known to be caused by heme (see Akane et al), which is a component of methemoglobin.

Response to Arguments

9. The response traverses the rejection. The response asserts that there is no basis for the position taken by the office that the '402 application does not provide support for the recitation

of a masking agent in general. The response asserts that hemoglobin and mathemoglobin are typical masking agents and that it is well understood that not all specific examples of a compound that has a particular activity or properties be recited in the specification for there to be support for a more general recitation of a compound having such activity or properties. This argument has been thoroughly reviewed but was found unpersuasive. The MPEP at 2163.03, II, states "Under 35 USC 120, the claims in a U.S. application are entitled to the benefit of the filing date of an earlier filed US application if the subject matter of the claim is disclosed in the manner provided by 35 USC 112, first paragraph in the earlier filed application". Additionally, the MPEP at section 2163.05, states "... in *Tronzo v. Biomet*, 156 F.3d 1154, 1159, 47 USPQ2d 1829, 1833 (Fed. Cir. 1998), the disclosure of a species in the parent application did not suffice to provide written description support for the genus in the child application. Similarly, see *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (generic and subgeneric claims in the U.S. application were not entitled to the benefit of foreign priority where the foreign application disclosed only two of the species encompassed by the broad generic claim and the subgeneric Markush claim that encompassed 21 compounds). The '402 application does not recite the broad generic term "masking agent", nor does it provide support for "suppressing a masking agent" or suppressing the interference of a masking agent. The '402 application provides no descriptive support for masking agents such as leukocyte esterases and bilirubin which are structurally and functionally different than hemoglobin and methemoglobin. The term thus encompasses a genus of structurally and functionally distinct molecules, which are not represented either structurally or functionally by hemoglobin or mathemoglobin. The term "masking agent" and suppression of any "masking agent" or suppression of the interference of any "masking agent" thus represents a

broadening of the invention in the '402 application and does not find support in the '402 application under the written description requirement of 35 USC 112, first paragraph.

The response further asserts that Harvey does not teach the claimed invention because Harvey does not teach adding the required components to a test sample as is used in the specification and the claims because the nucleic acid is applied to absorbent paper and that the nucleic acid must be released from the support to create a test sample. This argument has been thoroughly reviewed but was found unpersuasive. The instant claims only recite that the test sample contains nucleic acid, which is taught by Harvey. The instant specification does not provide a specific definition for a "test sample" but the term "sample" is defined as substances containing or presumed to contain nucleic acid, including bodily fluids (page 6). Further, the instantly rejected claims simply recite that the test sample containing nucleic acid is contacted with an amount of a divalent metal chelator (dependent claims include EDTA) and a chelator enhancing component (dependent claims include guanidine), which is taught by Harvey (see example 6, blood – test sample containing nucleic aid- is collected in a tube containing EDTA – divalent metal chelator- and a square containing guanidine –chelator enhancing component- is added). Therefore, Harvey specifically teaches contacting a test sample with a chelator and chelator enhancing component and anticipates the instantly pending claims. For these reasons and the reasons already made of record, the rejection is maintained.

10. Claims 37-39, 46, and 47 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Harvey I (Harvey et al; US Patent 6,168, 922; 102(e) date: 4/9/1997) or in the alternative under 35 U.S.C. 102(b) as being anticipated by Harvey II (Harvey et al; US Patent

5,939,259); as evidenced by Collis and as defined by Akane et al (Forensic Science, vol. 39, pp 362-372, 1994).

The claims are drawn to a method of improving hybridization of nucleic acids by suppressing specific masking agents (claim 37) comprising contacting the test sample with an amount of a divalent metal chelator and a chelator-enhancing component. With regard to claim 37, the recitation of "test nucleic acid" and "target nucleic acid" are interpreted to be any nucleic acid molecule, respectively.

With regard to claims 37-39, 46 and 47, Harvey I and II teach and claim methods and devices for collecting, storing, and purifying nucleic acids such as DNA or RNA from fluid samples for subsequent genetic characterization by conventional amplification methods (see abstract, claims 1-34 of Harvey I, claims 1-12 of Harvey II). Harvey I and II specifically teach that the nucleic acids can be either from an untreated blood source such as saliva, serum or urine, or a treated blood source (see abstract, col. 2, lines 54-65) that has naturally occurring nucleic acid amplification inhibitors present, such as hemoglobin. Harvey et al teach that the device, 903 paper, should be composed of an absorbent material that does not bind nucleic acids irreversibly, impregnated with a chaotropic salt such as guanidine isothiocyanate or sodium perchlorate. Harvey et al specifically teach a method whereby a square of treated paper (treated with guanidine thiocyanate – see example 1, col. 5) is added to blood which has been collected in a tube containing EDTA (see example 6). Harvey et al teach that DNA was extracted from the paper and subjected to PCR (see figure 7, lanes 9 and 10 which show amplification of product). It is noted that Harvey et al does not teach suppressing the effects of methemoglobin, however such is considered a component of blood samples along with hemoglobin and other oxidation

and breakdown products thereof. Hemoglobin was known to inhibit PCR reactions at the time of the invention. Further, such inhibition was known to be caused by heme (see Akane et al), which is a component of methemoglobin. Although Harvey does not specifically recite improvement of hybridization by suppressing a masking agent, as evidenced by Collis ('185), nucleic acid hybridization inhibitory substances are derived from heme and hematin which are commonly found in blood samples (col. 1, lines 27-30). Collis teaches that adding chaotropic agents such as guanidine thiocyanate in samples containing inhibitors overcomes this problem (para bridging cols 2-3). With regard to claim 37 which preamble recites "a method of improving hybridization of nucleic acids", such recitations do not distinguish the instantly claimed methods from those of Harvey because Harvey teaches the positive process steps of the claimed method and thus the effects of such necessarily follow.

11. Claims 1-6, 8-13, 15-22, 24-29, 31-41, 43-44, 46-48 and 50-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Sigman et al (WO 93/03167, 2/18/1993) as evidenced by Harvey I or II or Collis.

The claims are drawn to a method of suppressing the interference of specific masking agents on a molecular assay of a nucleic acid containing test sample (claims 1 and 17) or a method of improving hybridization of nucleic acids by suppressing specific masking agents (claim 37) comprising contacting the test sample with an amount of a divalent metal chelator and a chelator-enhancing component. With regard to claim 37, the recitation of "test nucleic acid" and "target nucleic acid" are interpreted to be any nucleic acid molecule, respectively.

Sigman teaches a method of isolating and preserving DNA. Sigman teaches that there is a need to isolate and prevent degradation of DNA in blood samples from patients suspected of infection with parasites, such as T. Cruzi (eukaryotic DNA; claims 15-16, 34-35, and 46-47) or other infectious agents during storage (p. 3, lines 16-19). With regard to claims 1-3, 6, 17-19, 22, and 37-39, Sigman teaches that isolation and storage comprise contacting a biological sample containing DNA in cells with a buffer (aqueous solution) containing a nonamphipathic chaotropic salt (chelator enhancing component) such as guanidine thiocyanate or guanidine chloride and a concentration of a chelating agent (divalent metal chelator; claims 2, 3, 18, 19, 38, and 39) such as EDTA (see p. 9, lines 1-11).

With regard to claims 31-33, Sigman teaches that the method is suitable for use on any biological sample including human blood, urine, sputum and lymphatic fluid (p. 12, lines 15-21).

With regard to claims 4, 5, 8, 9, 20, 21, 24, 25, 40, 41, 43, and 44, Sigman teaches that preferably, the guanidinium chloride is present in at least 3 molar concentration (this concentration anticipates claim 8 [24, 43] as the range in claim 8 recites a 20 fold difference in concentration, such that 'about' 0.1-2M is broadly interpreted to encompass 3 M; with regard to claims 9 and 25, "at least about 1M" is interpreted to encompass a minimum of about 1M with a maximum concentration above "about 1M" as limited by the upper limitation in claim 8, which includes 3M) and the chelating agent in at least 0.1 molar concentration (claims 4, 20, and 40) in the mixture of the biological sample and storage buffer (with regard to claims 5, 21, and 41, Sigman teaches a solution that contains a divalent metal chelator in an amount of at least about 0.01M). Sigman specifically teaches that human intravenous blood was freshly drawn and added

to a tube containing guanidinium chloride and EDTA so that the final concentration of each was 3M and .1M respectively (p. 26, Example 1).

With regard to claims 17, 36, 48, 50, and 51, Sigman teaches conducting PCR amplification on isolated DNA (page 20). Sigman specifically that the DNA was extracted (extracting molecular analytes of interest) and PCR amplified (conducting a molecular assay) (page 36, lines 10-15). As Sigman teaches that there is a need to prevent DNA degradation in blood samples (p. 3, lines 16-20), the method of Sigman inherently improves signal response. Sigman specifically teaches a polymerase chain reaction on cleaved minicircle DNA extracted from a blood/GnCl/ EDTA (GEB lysate) sample (see examples 3 and 4). Sigman teaches that using the GEB lysate, PCR amplification of extracted minicircles was sensitive enough that a single T.cruzi cell could be detected in 20 ml of blood (p. 35). With regard to claim 37, the method of Sigman is interpreted to improve hybridization of primers to intact DNA as compared to hybridization that would occur with regard to degraded DNA.

With regard to the preamble in claims 1, 17, and 37 as well as claims 10-13 and 26-29, although Sigman does not specifically teach inhibition of masking agents set forth in the claim, such is considered a property of the method of Sigman as the addition of the reagents taught by Sigman to the sample taught by Sigman provides for suppression of such masking agents. As evidenced by Harvey ('259), common inhibitors, such as hemoglobin, to nucleic acid amplification can be found in buccal swabs, plasma, serum, sputum, urine and whole blood samples (column 3, lines 55-60). Harvey also teaches that chaotropic salts, such as guanidine thiocyanate (GuSCN) can overcome the problem of hemoglobin inhibition. As evidenced by Collis ('185), nucleic acid hybridization inhibitory substances are derived from heme and

hematin which are commonly found in blood samples (col. 1, lines 27-30). Collis teaches that adding chaotropic agents such as guanidine thiocyanate in samples containing inhibitors overcomes this problem (para bridging cols 2-3). With regard to claim 17, which preamble recites "a method of improving the signal response of a molecular assay" and claim 37 which preamble recites "a method of improving hybridization of nucleic acids", such recitations do not distinguish the instantly claimed methods from those of Sigman because Sigman teaches the positive process steps of the claimed method in the same order, and thus the effects of such necessarily follow.

Response to Arguments

12. The response traverses the rejection. The response asserts that Sigman does not specifically disclose the interference of a masking agent and that therefore, any suppression of interference is unintentional and inadvertent and therefore cannot anticipate the claimed invention. This argument has been thoroughly reviewed but was found unpersuasive. Firstly, the mixture used by Sigman was specifically taught to be used to isolate and preserve the DNA for future use. Sigman, at page 3, specifically teaches use of a buffer containing the claimed components to preserve the DNA from degradation. Secondly, as stated in the MPEP, section 2112 II: "There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference." This is evidenced by the teachings of Harvey and Collis. The response's assertion that the term "molecular assay", in light of the specification, must be read to mean an assay in which sequence specific recognition plays some role is not found persuasive. Sigman does teach assays in which sequence specific recognition plays a role (PCR). Further,

the specification provides no express definition of a molecular assay and instead states that the invention relates generally to DNA analysis (page 1), assays of nucleic acids in bodily samples (page 3), hybridization assays (page 3), probe based diagnostics, microarray/Chip methods, PCR, amplification, SNP analysis, DNA sequencing, drug discovery, drug response genes, (page 4, lines 19-22), NASBA, SDA, and genetic transformation testing (page 5). As such, no specific definition is given. Instead, the specification provides very broad and general teachings of molecular assays, and therefore the term "molecular assay" can be broadly and reasonably interpreted to be any assay involving DNA. The response's assertion that Sigman does not teach or disclose improvement in hybridization because Sigman focuses on methods by which DNA is subject to chemical cleavage and that anticipation is unintended and accidental is not found persuasive. As already noted above, the mixture used by Sigman was specifically taught to be used to isolate and preserve the DNA for future use, for specifically: PCR - which uses hybridization. As stated in the MPEP, section 2112 II: "There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference."

Claim Rejections - 35 USC § 103

13. Claims 7, 23, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harvey et al.

Harvey et al teach and claim methods and devices for collecting, storing, and purifying nucleic acids such as DNA or RNA from fluid samples for subsequent genetic characterization by conventional amplification methods (see abstract, claims 1-34). Harvey et al specifically

teach that the nucleic acids can be either from an untreated blood source such as saliva, serum or urine, or a treated blood source (see abstract, col. 2, lines 54-65) that has naturally occurring nucleic acid amplification inhibitors present, such as hemoglobin. Harvey et al teach that the device, 903 paper, should be composed of an absorbent material that does not bind nucleic acids irreversibly, impregnated with a chaotropic salt such as guanidine isothiocyanate or sodium perchlorate. Harvey et al specifically teach a method whereby a square of treated paper (treated with guanidine thiocyanate – see example 1, col. 5) is added to blood which has been collected in a tube containing EDTA (see example 6). Harvey et al teach that DNA was extracted from the paper and subjected to PCR (see figure 7, lanes 9 and 10 which show amplification of product). Harvey does not specifically exemplify paper treated with sodium perchlorate, however Harvey et al teach that such would be a suitable chaotropic agent. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the device of Harvey et al, treated with sodium perchlorate as Harvey et al teach that such would be a suitable device (see col. 3, lines 16-36) for use in the method of Harvey et al.

Response to Arguments

14. The response traverses the rejection. The response asserts that all claim limitations must be considered in evaluating non-obviousness of an invention in light of the prior art and that as indicated previously, Harvey does not teach the use of the agents taught by Harvey in a test sample. This argument has been thoroughly reviewed but was not found persuasive for the reasons made of record above. As noted previously, Harvey teaches a method whereby a test sample containing nucleic aid- is collected in a tube containing EDTA –divalent metal chelator-

and a square containing a chaotropic agent –chelator enhancing component- is added. Although Harvey does not specifically exemplify 903 paper with sodium perchlorate, Harvey et al teach that the device, 903 paper, should be composed of an absorbent material that does not bind nucleic acids irreversibly, impregnated with a chaotropic salt such as sodium perchlorate. For these reasons and the reasons already made of record, the rejection is maintained.

15. Claims 14, 30, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang, or Sigman, or Harvey I, or Harvey II, (in the alternative), each in view of Heath (US Patent 5,973,137).

Zhang teaches a method comprising adding a lysis buffer containing 2.5-5M guanidine thiocyanate and 100mM EDTA and .5% of a detergent to an equal volume of sample (serum) that contains nucleic acids (test nucleic acids) (it is noted that the final concentration of buffer would be 1.25-2.5 M GnSCN and .05M EDTA) (p. 14, lines 8-30) and subsequently adding nucleic acid amplification probes (target nucleic acid) and paramagnetic beads to the solution containing lysis buffer and nucleic acids from the sample. Zhang specifically teaches that hybridization occurs between the nucleic acid from the sample and the probes (p.17, lines 19-20). Zhang specifically teaches that the method can be used for detection of genetic variations in samples from patients with genetic diseases or neoplasia (page 4, lines 13-23, page 5, lines 12-19- eukaryotic DNA). Zhang specifically teaches that samples for the method include whole blood, separated white blood cells, sputum, tissue biopsies, throat swabbings, urine, and serum (see page 13, lines 34-37, page 14, line 11) (claims 31-33).

Sigman teaches that there is a need to isolate and prevent degradation of DNA in blood samples from patients suspected of infection with parasites, such as T. Cruzi (eukaryotic DNA) or other infectious agents during storage (p. 3, lines 16-19). Sigman teaches that isolation and storage comprise contacting a biological sample containing DNA in cells with a buffer (aqueous solution) containing a nonamphipathic chaotropic salt (chelator enhancing component) such as guanidine thiocyanate or guanidine chloride and a concentration of a chelating agent (divalent metal chelator) such as EDTA (see p. 9, lines 1-11). Sigman teaches that the method is suitable for use on any biological sample including human blood, urine, sputum and lymphatic fluid (p. 12, lines 15-21). Sigman teaches performing PCR with the preserved nucleic acid.

Harvey I and II teach and claim methods and devices for collecting, storing, and purifying nucleic acids such as DNA or RNA from fluid samples for subsequent genetic characterization by conventional amplification methods (see abstract, claims 1-34). Harvey I and II teach that the device, 903 paper, should be composed of an absorbent material that does not bind nucleic acids irreversibly, impregnated with a chaotropic salt such as guanidine isothiocyanate or sodium perchlorate. Harvey I and II specifically teach a method whereby a square of treated paper (treated with guanidine thiocyanate – see example 1, col. 5) is added to blood which has been collected in a tube containing EDTA (see example 6). Harvey et al teach that DNA was extracted from the paper and subjected to PCR.

Neither Zhang nor Sigman nor Harvey I or II teach the addition of an enzyme inactivating component, however Heath teaches that nucleic acid isolation and preservation methods should include anionic detergents, such as SDS or sarkosyl in an amount of .5-3% (col. 6, lines 7-20) for the purpose of lysing cells or solubilizing proteins and lipids as well as denature

proteins. Therefor it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Zhang or Sigman or Harvey I or II by the addition of SDS or sarkosyl to the composition comprising the EDTA and guanidine. The ordinary artisan would have been motivated to modify the method of Zhang or Sigman or Harvey I or II with the addition of SDS or sarkosyl to the composition containing EDTA and guanidine because Heath teaches that such reagents solubilize and denature proteins.

16. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang, or Sigman, or Harvey I, or Harvey II, (in the alternative), each in view of Ahern (The Scientist; vol. 9, pp 1-5-from the internet; 1995).

Zhang teaches a method comprising adding a lysis buffer containing 2.5-5M guanidine thiocyanate and 100mM EDTA and .5% of a detergent to an equal volume of sample (serum) that contains nucleic acids (test nucleic acids) (it is noted that the final concentration of buffer would be 1.25-2.5 M GnSCN and .05M EDTA) (p. 14, lines 8-30).

Sigman teaches a method of isolating and preserving DNA. Sigman teaches that there is a need to isolate and prevent degradation of DNA in blood samples from patients suspected of infection with parasites, such as T. Cruzi (eukaryotic DNA) or other infectious agents during storage (p. 3, lines 16-19). Sigman teaches that isolation and storage comprise contacting a biological sample containing DNA in cells with a buffer (aqueous solution) containing a nonamphipathic chaotropic salt (chelator enhancing component) such as guanidine thiocyanate or guanidine chloride and a concentration of a chelating agent. Sigman teaches performing PCR with the preserved nucleic acid.

Harvey I and II teach and claim methods and devices for collecting, storing, and purifying nucleic acids such as DNA or RNA from fluid samples for subsequent genetic characterization by conventional amplification methods (see abstract, claims 1-34). Harvey I and II teach that the device, 903 paper, should be composed of an absorbent material that does not bind nucleic acids irreversibly, impregnated with a chaotropic salt such as guanidine isothiocyanate or sodium perchlorate. Harvey I and II specifically teach a method whereby a square of treated paper (treated with guanidine thiocyanate – see example 1, col. 5) is added to blood which has been collected in a tube containing EDTA (see example 6). Harvey et al teach that DNA was extracted from the paper and subjected to PCR.

Neither Zhang nor Sigman nor Harvey I or II teach the reagents or device in kit format, however Ahern teaches that providing reagents and products in kit format offer scientists the opportunity to better manage their time, and that such kits are convenient. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to package the reagent of Zhang or Sigman, or the device of Harvey I or II in kit format for the purposes of providing premade reagents which are convenient and will save researchers time, as taught by Ahern.

Response to Arguments

17. The response traverses the rejection. The response asserts that since neither Sigman, nor Harvey teach suppression of interference by a masking agent in a molecular assay such as PCR, the primary references in combination with Ahern fail to teach or suggest the invention in it's entirety. This argument has been thoroughly reviewed but was found unpersuasive as the use for

a kit carries no patentable weight. The kit is simply recited to include a reagent which suppresses the interference of a masking agent. The reagents taught by Sigman and Harvey are reagents which would suppress the interference of a masking agent on a molecular assay. The packaging of such kits is obvious over the teachings of Zhang, Sigman, Harvey I or Harvey II, each in view of Ahern, as set forth above. The instructions in the instantly claimed kit are considered printed material and are not given patentable weight. The inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004) (holding that an inventor could not patent known kits by simply attaching a new set of instructions to that product). For these reasons and the reasons already made of record, the rejection is maintained.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,458,546. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are coextensive in scope. The claimed method steps of the instant application encompass the more narrow methods steps of the claims of the '546 patent. The claims of the '546 patent do not recite a method of suppressing a masking agent, however, the claims are drawn to a method of preserving a nucleic acid in a bodily fluid by adding a reagent containing, for example, EDTA and guanidine thiocyanate to a bodily fluid. Guanidine thiocyanate is a chaotropic agent known to inhibit hybridization inhibitors such as hemoglobin, therefore, suppressing a masking agent is considered a property of the claimed method of the '546 patent.

Response to Arguments

20. The response traverses the rejection. The response asserts that the claims of the '546 application do not recite a method of suppressing a masking agent and that preservation of a sample cannot necessarily be equated with a masking agent. This argument has been thoroughly reviewed but was found unpersuasive as the method steps used in each method are coextensive in scope. The claimed method steps of the instant application encompass the more narrow methods steps of the claims of the '546 patent. The instantly claimed invention encompasses addition of an amount of guanidine, lithium chloride, sodium salicylate, sodium perchlorate or sodium thiocyanate, and an amount of EDTA, EGTA, or BAPTA to a bodily fluid containing nucleic acid. As noted in the instant specification, at page 3, "upon contact of with the divalent metal chelator and the chelator enhancing component, the masking agents are suppressed".

Claim 1 of the '546 patent is drawn to adding an amount of guanidine, lithium chloride, sodium salicylate, sodium perchlorate or sodium thiocyanate, and an amount of EDTA, EGTA, or BAPTA to a bodily fluid to. It is further noted that instant dependent claims 4 and 8 are drawn to concentrations that are recited in the preservative solution of claim 1 of the '546 patent. As guanidine isothocyanate is a chaotropic agent which inhibits masking agents forth in the claims, the suppression of a masking agent is considered a property of the claimed method of the '546 patent, as exemplified by the teachings of '546 that the invention "has been found to surprisingly modulate the effect of hemoglobin, e.g., methemoglobin, interference on nucleic acid assays such as PCR..." For these reasons and the reasons already made of record, the rejection is maintained.

21. Claims 17-48, 50 and 51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,458,546 in view of Sigman.

Instant claim 17 is drawn to a method of improving the signal response of a molecular assay by interfering with a masking agent by adding a divalent metal chelator (further drawn to adding such in solution in the range of from about 0.001M to 0.1M) and a chelator enhancing component (further drawn to adding such in solution in the range of from about 0.1M to 2M) to a test sample, which can be a biological fluid, extracting molecular analytes of interest from the sample, and conducting a molecular assay on the extracted molecular analytes. Instant claim 37 is drawn to a method of improving hybridization by suppressing a masking agent comprising adding a divalent metal chelator (further drawn to adding such in solution in the range of from

about 0.001M to 0.1M) and a chelator enhancing component (further drawn to adding such in solution in the range of from about 0.1M to 2M) to a test nucleic acid to form a test solution and contacting the test solution with a target such that hybridization occurs.

Claims 1-8 of the '546 patent are drawn to preserving nucleic acids in a biological fluid by contacting the biological fluid with a solution containing a divalent metal chelator in the range of from about 0.001M to about 0.1M and a chelator enhancing component in the range of from about 0.1M to about 2M. Although the claims of the '546 patent do not disclose extracting the nucleic acids and conducting a molecular assay involving hybridization or PCR on the extracted nucleic acids, Sigman teaches a method of isolating and preserving DNA and extracting the isolated and preserved DNA to perform molecular assays, such as hybridization and PCR on the extracted DNA (p. 3, lines 16-19). Sigman specifically teaches that the DNA was extracted (extracting molecular analytes of interest) and electrophoresed (conducting a molecular assay) and T.cruzi nucleic acids were identified. Sigman teaches that there is a need to prepare the DNA for amplification (p. 3, lines 20-21). Sigman specifically teaches a polymerase chain reaction on cleaved minicircle DNA extracted from a blood/GnCl/ EDTA (GEB lysate) sample (see examples 3 and 4). Sigman teaches that using the GEB lysate, PCR amplification of extracted minicircles was sensitive enough that a single T.cruzi cell could be detected in 20 ml of blood (p. 35). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to extract and assay the nucleic acids preserved in the claims of the '546 patent for the purpose of sequencing, or identifying the origin of the DNA preserved, for example to identify infective pathogens in a sample of blood from a patient as taught by Sigman. The ordinary artisan would have been motivated to extract and

assay the nucleic acids preserved in the method of the '546 patent for the purpose of identifying such nucleic acids for diagnosing a pathogenic infection, for example. Guanidine thiocyanate is a chaotropic agent known to reduce the effects of hybridization and PCR inhibitors, therefore, suppressing a masking agent is considered a property of the claimed method of the '546 patent.

Response to Arguments

22. The response traverses the rejection. The response asserts that for the reasons already given, Sigman does not disclose or suggest the suppression by a masking agent or the improvement of a signal response due to the suppression of interference by a masking agent, the combination of Baker and Sigman does not provide basis for the rejection. This argument has been thoroughly reviewed but was not found persuasive for the reasons made of record in the rejection above as well as with regard to the '546 patent in sections 18-19, and Sigman in sections 11-12 of the instant office action.

23. Claim 49 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,458,546 in view of Ahern.

Claims 1-8 of the '546 patent are drawn to preserving nucleic acids in a biological fluid by contacting the biological fluid with a solution containing a divalent metal chelator in the range of from about 0.001M to about 0.1M and a chelator enhancing component in the range of from about 0.1M to about 2M. Although the claims of the '546 patent do not disclose the preservative solution in kit format, Ahern teaches that providing reagents and products in kit format offer scientists the opportunity to better manage their time, and that such kits are

convenient. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to package the reagent of the '546 patent in kit format for the purposes of providing premade reagents which are convenient and will save researchers time, as taught by Ahern. It is noted that the "use for" the kit carries no patentable weight. Guanidine thiocyanate is a chaotropic agent known to inhibit proteases as well as heme compounds, therefore, suppressing a masking agent is considered a property of the preservative solution recited in the claimed methods of the '546 patent.

Response to Arguments

24. The response traverses the rejection. The response asserts that there is no teaching of the kit of claim 49 when claims 1-8 of the '546 patent and Ahern are combined as the claims 1-8 of '546 patent do not teach or suggest suppression of a masking agent. This argument has been thoroughly reviewed but was found unpersuasive because the use for the kit carries no patentable weight. The kit is simply recited to include a reagent which suppresses the interference of a masking agent. The reagents taught by '546 claims are reagents which would suppress the interference of a masking agent on a molecular assay. As noted in the instant specification, at page 3, "upon contact of with the divalent metal chelator and the chelator enhancing component, the masking agents are suppressed". The packaging of such kits is obvious over the teachings of claims 1-8 of the '546 patent, in view of Ahern, as set forth above. The instructions in the instantly claimed kit are considered printed material and are not given patentable weight. The inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions

in a kit. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004) (holding that an inventor could not patent known kits by simply attaching new set of instructions to that product). For these reasons and the reasons already made of record, the rejection is maintained

25. Claim 49 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 19 of copending Application No.11/138,543. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 49 of the instant application is drawn to a kit that comprises a reagent for suppressing the interference of a masking agent on a molecular assay and instructions for use. As defined by the specification such a reagent includes a divalent metal chelator, such as EDTA, EGTA, or BAPTA, and/or a chelator enhancing component, such as lithium chloride, guanidine, sodium thiocyanate, sodium salicylate, and sodium perchlorate. As noted in the instant specification, at page 3, "upon contact of with the divalent metal chelator and the chelator enhancing component, the masking agents are suppressed". Claim 19 of the '543 application is drawn to a kit comprising a preservative composition comprising an amount of a divalent metal chelator, such as EDTA, EGTA, or BAPTA, in the range of about .001M to 2 M and a chelator enhancing component, such as lithium chloride, guanidinium chloride, guanidinium thiocyanate, sodium thiocyanate, sodium salicylate, and sodium perchlorate, in the range of from about 0.1M to 10 M; a vessel for collecting a fluid; and instructions for use. It is noted that claim 19 of the '543 application is sufficiently broad such that the vessel could contain the preservative composition. The vessel is not recited to contain any specific composition and is not limited to containing a bodily fluid. As such, although instant claim 49 does not recite a container, the

reagent would necessarily be contained in a container. Alternatively, the vessel in claim 19 of the '543 application could be a second container. Although the kit in instant claim 49 does not specifically recite a second container, it would have been prima facie obvious to one of ordinary skill in the art to include a container or vessel, in the kit of instant claim 49 so as to provide a container for conducting the molecular assay. The kits are therefore coextensive in scope and not patentably distinct from each other. The use for a kit is given no patentable weight. It is noted that the instructions in each kit are given no patentable weight as they provide an intended use for the claimed kits.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

26. The response traverses the rejection. The response asserts that there is no teaching or suggestion of the suppression of the specific masking agents recited in claim 49. The response asserts that such rejection is analogous to a rejection under 35 USC 103 which means that there is no obviousness type double patenting. This argument has been thoroughly reviewed but was found unpersuasive. Instant claim 49, as exemplified by claims 1-9, 17-25, etc encompass a kit with the same components as that of claim 19 of the '543 application. As noted in the instant specification, at page 3, "upon contact of with the divalent metal chelator and the chelator enhancing component, the masking agents are suppressed" (such divalent metal chelator and chelator enhancing components of the claimed kit of the '543 application). With regard to the

analogy to a rejection under 35 USC 103, it is noted that the MPEP, section 2144 "Rationale different from applicant's is permissible" states that rationale can be different from applicant's:

> The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) (discussed below); In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991) (discussed below). Although Ex parte Levengood, 28 USPQ2d 1300, 1302 (Bd. Pat. App. & Inter. 1993) states that obviousness cannot be established by combining references "without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done" (emphasis added), reading the quotation in context it is clear that while there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.

Accordingly, as the kit in the instant application and the kit of the '543 application are coextensive in scope, and the instructions for each kit is given no patentable weight and does not distinguish the kits, the rejection is maintained.

27. Claim 49 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12, 13, 17, and 18 of copending Application No. 11/138,543 in view of Ahern. Claim 49 of the instant application is drawn to a kit that comprises a reagent for suppressing the interference of a masking agent on a molecular assay and instructions for use. As defined by the specification such a reagent includes a divalent metal chelator, such as EDTA, EGTA, or BAPTA and/or a chelator enhancing component, such as lithium chloride, guanidine, sodium thiocyanate, sodium salicylate, and sodium perchlorate. Such a reagent can also include an enzyme inactivating component, such as manganese chloride, sarkosyl, and SDS. Claims 12 and 18 of the '543 application are drawn to a preservative composition comprising an amount of a divalent metal chelator, such as EDTA, EGTA, or BAPTA, in the range of about .001M to 2 M, or more specifically at least .01M; and a chelator enhancing component, such as lithium chloride, guanidinium chloride, guanidinium thiocyanate,

sodium thiocyanate, sodium salicylate, and sodium perchlorate, in the range of from about 0.1M to 10 M, more specifically at least 1 M. Claims 13 and 17 are further drawn the composition containing an enzyme inactivating component, such as manganese chloride, sarkosyl, and SDS, in the range of up to 5% molar concentration. As such, the reagent in the kit of instant claim 49 and the composition of claims 12, 13, 17, 18 of the '543 application are coextensive in scope. Claims 12, 13, 17, and 18 of the '543 application do not recite packaging the composition in kit format, however Ahern teaches that providing reagents and products in kit format offers scientists the opportunity to better manage their time, and that such kits are convenient. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to package the reagent composition of the '543 application in kit format for the purposes of providing premade reagents which are convenient and will save researchers time, as taught by Ahern. It is noted that the "use for" the kit carries no patentable weight.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

28. The response traverses the rejection. The response asserts that there is no teaching or suggestion of the suppression of the specific masking agents recited in claim 49 in the claims of the '543 application. The response further asserts that Ahern doe not provide the information necessary to create the obviousness type double patenting rejection, which is considered to be analogous to a rejection under 35 USC 103. These arguments have been thoroughly reviewed but were found unpersuasive for the reasons already made of record above.

Conclusion

29. No claims are allowable over the cited prior art.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Jehanne Sitton

Jehanne Sitton
Primary Examiner
Art Unit 1634

5/12/06